

CLAIMS

1. In a method for manufacturing TBO product comprising sequentially the steps of:

(a) oxidizing the starting material *N,N*-dimethyl-*p*-phenylenediamine, in a first reaction mixture;

5 (b) introducing a source of sulfur-containing nucleophile into said first reaction mixture, to form a first intermediate, substituted *S*-phenyl thiosulfate;

(c) further oxidizing and condensing said first intermediate with *o*-toluidine, to form a second intermediate, substituted *S*-indaminy l thiosulfate;

10 (d) further oxidizing said second intermediate, to form a TBO-containing reaction product in a third reaction mixture;

(e) introducing a TBO-complexing agent into at least one of said reaction mixtures; and

(f) separating the TBO-containing reaction product from said third reaction mixture;

the improvement comprising sequentially:

15 (a) oxidizing a starting material, comprised of at least one compound selected from the group consisting of *N,N*-dimethyl-*p*-phenylenediamine and *N*-dimethyl-*p*-phenylenediamine, in the presence of *o*-toluidine in a first reaction mixture to form a first intermediate, an indamine, without forming *S*-phenyl thiosulfate; and then

(b) introducing a source of sulfur-containing nucleophile into said first reaction mixture form a second intermediate, *S*-indaminy l thiosulfate.

2. A new composition of matter, comprising:

TBO, which has the ring methyl group at the C-2 position, as at least 73% by weight of the total organic dye content of said composition.

3. A process for manufacturing the composition of Claim 2 including the steps of :

- 5 (a) synthesizing an indamine; and
(b) synthesizing an *S*-indaminyll thiosulfate;

4. The process of Claim 4 wherein said step of synthesizing an indamine further comprises the step of oxidizing a solution of *o*-toluidine and a solution of *N,N*-dimethyl-*p*-phenylenediamine in the presence of an acid and oxidizing agent.

- 10 5. A method for identification of dysplastic tissue comprising:

the step of applying to human tissue the TBO product of Claim 2.

6. A method for treating dysplastic tissue comprising:

the step of applying to human tissue the TBO product of Claim 2.

7. The method for treating dysplastic tissue of Claim 6 further comprising:

15 modifying the incidence of light to control phototoxic effects.

8. The method for treating dysplastic tissue of Claim 6 further comprising:

the step of mixing a chemotherapeutic agent with said TBO product of Claim 4.

9. A new composition of matter, comprising:

the *N*-demethylated derivative of TBO, in which the *N*-demethylated derivatives have

the ring methyl group at the C-2 position, comprises at least 73% by weight of the total organic dye content of said composition.

10. A process for manufacturing the composition of Claim 9 including the steps of :

(a) synthesizing an indamine; and

(b) synthesizing an *S*-indaminyI thiosulfate;

11. The process of Claim 11 wherein said step of synthesizing an indamine further comprises the step of oxidizing a solution of *o*-toluidine and a solution of *N*-dimethyl-*p*-phenylenediamine in the presence of an acid and oxidizing agent.

12. A method for identification of dysplastic tissue comprising:

the step of applying to human tissue the TBO product of Claim 9.

13. A method for treating dysplastic tissue comprising:

the step of applying to human tissue the TBO product of Claim 9.

14. The method for treating dysplastic tissue of Claim 13 further comprising:

modifying the incidence of light to control phototoxic effects.

15. The method for treating dysplastic tissue of Claim 13 further comprising:

the step of mixing a chemotherapeutic agent with said TBO product of Claim 9.

5 16. A new composition of matter, comprising:

TBO, which has the ring methyl group at the C-2 position; and

the *N*-demethylated derivative of TBO having the ring methyl group at the C-2 position;

in which said TBO and said *N*-demethylated derivative comprises at least 70% by weight of the total organic dye content of said composition.

10 17. A process for manufacturing the composition of Claim 16 including the steps of :

(a) synthesizing an indamine; and

(b) synthesizing an *S*-indaminy l thiosulfate;

15 18. The process of Claim 17 wherein said step of synthesizing an indamine further comprises the step of oxidizing a solution of *o*-toluidine and a solution of *N,N*-dimethyl-*p*-phenylenediamine and *N*-dimethyl-*p*-phenylenediamine in the presence of an acid and oxidizing agent.

19. A method for identification of dysplastic tissue comprising:

the step of applying to human tissue the TBO product of Claim 16.

20. A method for treating dysplastic tissue comprising
the step of applying to human tissue the TBO product of Claim 16.
21. The method for treating dysplastic tissue of Claim 20 further comprising:
modifying the incidence of light to control phototoxic effects.
- 5 22. The method for treating dysplastic tissue of Claim 20 further comprising:
the step of mixing a chemotherapeutic agent with said TBO product of Claim 16.
23. In an HPLC method for analysis of a TBO dye product, said method including :
- (a) forming a TBO sample solution,
- (b) forming a mobile phase comprising a water-soluble salt of an organic acid,
- 10 (c) equilibrating an HPLC column with the mobile phase flow, and
- (d) injecting the sample solution into the HPLC column,

the improvement for identifying sample dye components and for assaying and determining the
purity of said sample, said improvement comprising:

forming said mobile phase as a composition including heptanesulfonic acid; and

15 forming a second mobile phase composition comprising 50% alcohol by volume.